

Amendments to the Claims

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1. (Currently Amended) A method for controlled delivery of parathyroid hormone to a patient in need thereof comprising:

implanting a medical device into the patient, the medical device comprising:

a substrate having a plurality of reservoirs,

a release system contained in each of the reservoirs, wherein the release system comprises parathyroid hormone, and

a plurality of discrete reservoir caps, each being in register with an opening of one of the reservoirs, separating the release system from an environment outside of the reservoirs, and preventing the parathyroid hormone from being released from the medical device;

passing an electric current through one or more of the discrete reservoir caps, via an electrical input lead and an electrical output lead which are electrically connected to said reservoir cap, to disintegrate the one or more discrete reservoir caps by electrothermal ablation, thereby to expose to the environment the release system contained in the one or more reservoirs corresponding to the disintegrated one or more reservoir caps; and

releasing a pharmaceutically effective amount of the parathyroid hormone from the one or more reservoirs corresponding to the disintegrated one or more reservoir caps.

2. (Previously Presented) The method of claim 1, wherein the parathyroid hormone is released intermittently from the medical device.
3. (Original) The method of claim 1, wherein the parathyroid hormone is released daily in intermittent doses of between about 10 and 300 μg .
4. (Original) The method of claim 3, wherein the daily intermittent doses are released over a period of ten months or more.
5. (Original) The method of claim 1, wherein the parathyroid hormone is released in a pulsatile manner, each pulse having a duration of less than four hours.
6. (Original) The method of claim 1, wherein the pharmaceutically effective amount of the parathyroid hormone, released over a first period of time, is effective to form bone tissue.
7. (Previously Presented) The method of claim 6, further comprising administering a pharmaceutically effective amount of a bone resorption inhibitor, released over a second period of time, to maintain bone tissue at a level present after the first period of time.
8. (Original) The method of claim 7, wherein the bone resorption inhibitor is selected from the group consisting of bisphosphonates, selective estrogen receptor modulators, calcitonins, vitamin D analogs, and calcium salts.
9. (Original) The method of claim 6, wherein the bone resorption inhibitor is administered orally.

10. (Original) The method of claim 6, wherein the bone resorption inhibitor is released from one or more reservoirs in the medical device.

11. (Cancelled).

12. (Currently Amended) An implantable device for controlled delivery of parathyroid hormone to a patient in need thereof comprising:

a substrate having a plurality of reservoirs;

a release system contained in each of the reservoirs, wherein the release system comprises parathyroid hormone;

a plurality of discrete reservoir caps, each reservoir cap comprising a metal film in register with an opening of one of the reservoirs, separating the release system from an environment outside of the reservoirs, and preventing the parathyroid hormone from being released from the implantable device; and

means for disintegrating one or more of the discrete reservoir caps by electrothermal ablation to release the parathyroid hormone from one or more of the reservoirs,

wherein the means for disintegrating comprises (i) an electrical input lead and an electrical output lead which are electrically connected to at least one of said reservoir caps, (ii) a power source, and (iii) a control means for controlling application of an electric current from the power source through said at least one of the reservoir caps, via the input and output leads.

13. (Original) The device of claim 12, which is able to release a pharmaceutically effective amount of parathyroid hormone once daily over a period of at least six months.

14. (Original) The device of claim 12, further comprising at least one reservoir which contains a second release system comprising a drug other than parathyroid hormone.
15. (Original) The device of claim 14, wherein the drug is an anti-resorptive agent.
16. (Original) The device of claim 12, wherein each of the reservoirs contains between about 10 and 300 μg of parathyroid hormone for release.
17. (Original) The device of claim 12, wherein the plurality of reservoirs comprises 300 or more reservoirs, each containing a release system comprising parathyroid hormone.
18. (Original) The device of claim 12, wherein the release system comprises parathyroid hormone in combination with a pharmaceutically acceptable excipient.
19. (Original) The device of claim 12, wherein the release system comprises parathyroid hormone suspended in a non-aqueous vehicle.
20. (Original) The device of claim 18, wherein the parathyroid hormone is dried or lyophilized with an excipient that promotes re-dissolution upon release.
21. (Original) The device of claim 18, wherein the excipient comprises polyethylene glycol having a molecular weight between about 100 and 10,000 Daltons.
- 22-26. (Cancelled).
27. (Original) The device of claim 12, further comprising a sensor.

28-31. (Cancelled).

32. (Original) The device of claim 12, capable of vaginal administration of the parathyroid hormone.

33. (Cancelled).

34. (Previously Presented) An implantable device for controlled delivery of parathyroid hormone to a patient in need thereof comprising:

a body having a plurality of reservoirs;

a release system contained in each of the reservoirs, wherein the release system comprises parathyroid hormone;

an electrically conductive reservoir cap covering a discrete, predefined opening in each reservoir;

a conducting input lead and a conducting output lead each of which are physically and electrically connected to each reservoir cap; and

a power source and a controller for selectively delivering an electric current through the reservoir cap via the conducting leads effective to rupture the reservoir cap and release a pharmaceutically effective amount of the parathyroid hormone from the reservoir.

35. (Original) The device of claim 34, wherein the release system comprises multiple layers of release system having different compositions.

36. (Previously Presented) The device of claim 34, wherein the release system comprises parathyroid hormone is in a dried or lyophilized form and a polyethylene glycol.

37. (Cancelled).

38. (Previously Presented) The device of claim 34, wherein the reservoir cap and the input and output leads provide upon the application of electrical current an increase in electrical current density in the reservoir cap relative to the current density in the input and output leads.

39. (Previously Presented) The device of claim 34, wherein the material forming the reservoir cap has a different electrical resistivity, thermal diffusivity, thermal conductivity, and/or a lower melting temperature than the material forming the input and output leads.

40. (Previously Presented) The device of claim 34, wherein the reservoir cap and the input and output leads provide upon the application of electrical current an increase in electrical current density in the reservoir cap relative to the current density in the input and output leads, and the material forming the reservoir cap has a different electrical resistivity, thermal diffusivity, thermal conductivity, and/or a lower melting temperature than the material forming the input and output leads.

41. (Previously Presented) The device of claim 12, wherein the body comprises silicon and the reservoir cap comprises at least one metal film.

42. (Previously Presented) The device of claim 41, wherein the reservoir cap comprises a multi-layer structure comprising platinum and titanium.